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DLA PIPER LLP (US)
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER	
OCHYLSKI, RYAN M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,023	WU ET AL.	
	Examiner	Art Unit	
	RYAN OCHYLSKI	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because the polymer jet feature as disclosed in [0037] of the instant specification is not shown in Figure 1 or any other drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: Paragraph [0003] specifies that electrospinning is a method of producing fibers with "diameters

ranging from 10 nm to 10 fun." Since "fun" cannot be said to be a measure of fiber diameter, appropriate correction is required.

3. Both the "direct current source" and "polymer jet" features are identified as being Item 9 in [0035] and [0037], respectively. It appears that the "polymer jet" should be Item 10, since Figure 1 already contains a label for Item 9 that appears to be the direct current source.

Claim Objections

4. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The liquid phase of Claim 18 is not further limited by the statement in Claim 19 that the liquid phase comprises one or a plurality of liquids, since a liquid phase would inherently comprise either one or a plurality of liquids.

5. Claims 18 and 22 are objected to because of the following informalities:

6. Claim 18 Line 1 should have one instance of "diameter" deleted.

7. Claim 22 Line 2 should have --poly-- directly in front of "(vinylidene fluoride-co-trifluouroethylene)."

8. Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-2, 4-11, 13-16, and 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US 2003/0054035), and in view of Kleinmeyer et al. (US 2002/0089094).

13. Note that Claims 1-14 are directed towards an apparatus and as such will be examined under such conditions. The material worked upon or the process of using the apparatus are viewed as recitation of intended use and are given little patentable weight (Please see MPEP 2114 R1-2115 R2 for further details). Specifically, the Examiner notes that Claims 4-10 are apparatus claims that merely material used in the apparatus, and thus do not further limit the apparatus, and the rejection of Claims 4-10 below should not be taken as an indication that the material used in Claims 4-10 are being given patentable weight.

14. Regarding Claims 1, 4-10, and 15, Chu et al. teach an apparatus (capable of handling the materials of instant Claims 4-10) and a method for fabricating polymer fibers, the method and apparatus comprising:

a) positioning an electrode near an orifice of a dispenser to form a gap between the electrode and the orifice ("the plate electrode is placed at a distance of about 10 mm from the spinneret" [0205]) containing a metastable electrically charged polymer dispersion ("conducting fluid, which contains the biodegradable polymer" [0195]), wherein the dispenser includes a proximal end and a distal end, where the proximal end defines an orifice (as shown by spinnerets 6 in Figure 2, and as best shown by Figure 4a, which the Examiner considers representative of all the spinnerets/dispensers of Chu et al.);

b) electrically pulling the polymer dispersion from the orifice by applying electric voltage via the electrode to the gap defined between the electrode and orifice ("The short distance between ... implies that the electrostatic potential could be fairly low ... By varying the electric potential of individual spinneret, the jet formation can be controlled and adjusted for individual spinnerets" [0205]); and

c) collecting the polymer fibers at a collector located at a distance from the gap and allowing the electropulled dispersion to solidify ("jet was formed and stabilized" [0224]) to form the polymer fibers ("The grounded target was a rotating drum [at a] distance from the tip of the electrode to the outside surface of the drum … form[ing] an interconnecting web of thin submicron diameter fibers" [0224]).

However, Chu et al. are silent on whether the polymer fibers are oriented polymer fibers.

In analogous art pertaining to electrospinning, Kleinmeyer et al. teach linearly orienting a solidifying extruded polymer via a sequentially biased electrostatic field for the benefit of providing a biomedical tissue growth support that is highly uniform in quality [0012].

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Kleinmeyer et al. with Chu et al. for the benefit of providing a biomedical tissue growth support that is highly uniform in quality.

15. Regarding Claims 2 and 16, Chu et al. teach that the dispenser is connected to a source of electric potential for charging the polymer dispersion ("positive high voltage (by Glassman High Voltage, Inc.) was applied" [0224]).

16. Regarding Claims 18-20, Chu et al. teach that the metastable dispersion is fabricated by dispersing a polymer in a liquid phase comprising one or a plurality of liquids ("slowly dissolving the polymer/monomer blend solution into the DMF solvent" [0224]; also

see [0190]).

17. Regarding Claims 11, 13-14, and 27-31, Chu et al. teach

- that the collector is grounded ("The grounded target was a rotating drum" [0224]),
- that the orifice is a capillary tip (as per the description in [0012], wherein the fluid is disclosed to be held by capillary action until the electrostatic field generates enough force to pull the droplet from the tip), wherein the Examiner considers the orifice diameter to obviously be inclusive of between 10 nanometers and 100 micrometers, since the process of Chu et al. as applied to Claims 1 and 15 above produces submicron fibers [0017];
- that the electric voltage applied to the electrode is between about 20 kV and 40 kV ("A 20 kV positive high voltage … was applied on the electrode" [0224]), and
- that the distance between the gap and the collector is between about 10 centimeters and 30 centimeters ("The distance from the tip of the electrode to the outside surface of the [collecting] drum was about 15 cm" [0224]).

18. Regarding Claim 21, Chu et al. teach that the metastable dispersion is fabricated stepwise by first mixing a polymer with a monomer in to make a polymer blend (but not explicitly dissolving the polymer in solvent), and then dispersing the polymer blend in the liquid phase ("slowly dissolving the polymer/monomer blend into the DMF solvent at

a room temperature" [0024]). Chu et al. further teach that additives (but not explicitly polymers) intended to be added to the metastable dispersion may first require dissolving in a solvent before dispersal in the liquid phase itself ("In loading the additives, the additive may need to be dissolved in a solvent…" [0129]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to fabricate the metastable dispersion by dissolving a polymer in a solvent to make a polymer solution, and dispersing the polymer solution in the liquid phase for the benefit of ensuring that the polymer becomes properly dispersed in the liquid phase so that the produced fiber product has a consistent composition and thus consistent properties.

19. Regarding Claim 22, Chu et al. teach that the polymer is poly(lactic acid-co-glycolic acid) ("A PLGA … membrane [comprising electrospun submicron fibers] was produce by a process similar to Example 1") [0232]).

20. Regarding Claims 23 and 24, Chu et al. teach that the polymer dispersion further comprises a compound, namely sodium chloride, for decreasing the stability of the metastable polymer dispersion ("The conducting fluid can optionally contain a salt which creates an excess charge effect to facilitate the electrospinning process ... includ[ing] NaCl" [0191]).

21. Regarding Claim 25, Chu et al. teach that the polymer dispersion further comprises biologically active molecules ("calcium hydroxyapetite can also be incorporated [into the conducting fluid" [0191]; also "one or more cell culture additives can be incorporated into the conducting fluid" [0191] as defined in [0130]).

22. Regarding Claim 26, Chu et al. teaches that the polymer dispersion further comprises at least one surfactant. ("In loading the additives, the additive may need to be dissolved in a solvent that may not be compatible with the solvent used in the electrospinning process. A block copolymer, acting as a surfactant, can be used to circumvent this difficulty" [0129]).

23. Claims 1-2, 4-16, 18-20, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childs (US 2,338,570), and in view of Kleinmeyer et al. (US 2002/0089094).

24. Regarding Claims 1, 4-10, and 15, Childs teaches an apparatus (capable of handling the materials of instant Claims 4-10) and a method for fabricating polymer fibers, the method and apparatus comprising:

a) positioning an electrode (17) near an orifice (32) of a dispenser (4) containing a metastable electrically charged polymer dispersion ("a highly charged cellulose derivative solution" Column 2 Lines 35-36) to form a gap between the electrode and the orifice (as shown by Figure 1), wherein the dispenser includes a proximal end and a distal end, where the proximal end defines an orifice (as shown by Figure 2);
b) electrically pulling the polymer dispersion from the orifice by applying electric voltage to the electrode with an electrode positioned near the orifice, wherein the electrode and the orifice define a gap therebetween ("into an electrostatic field maintained between the spinneret and a directing electrode of opposite potential" Column 2 Lines 38-41); and

c) collecting the polymer fibers at a collector located at a distance from the gap and allowing the electropulled dispersion to solidify, wherein the collector is positioned at a distance from the gap, to form the polymer fibers ("the cellulose derivative material is separated from the solution in the form of short fibers ... which are attracted to a dry, unsupported collecting tail of previously formed fibers" Column 2 Lines 41-46 and as shown in Figure 1; also "the sliver passes through guide 25 to a conventional cap spinning device 26 where it is wound and twisted" Column 4 Lines 49-58).

However, Childs is silent on whether the polymer fibers are oriented polymer fibers.

In analogous art pertaining to electrospinning, Kleinmeyer et al. teach linearly orienting a solidifying extruded polymer via a sequentially biased electrostatic field for the benefit of providing a biomedical tissue growth support that is highly uniform in quality [0012].

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Kleinmeyer et al. with Childs for the benefit of providing a biomedical tissue growth support that is highly uniform in quality.

25. Regarding Claims 2 and 16, Childs teaches that the dispenser is connected to a source of electric potential for charging the polymer dispersion ("Leads 15 and 16 are connected to a suitable source of potential … thus assuring that the solution emerges from the spinneret with a heavy electrostatic charge" Column 4 Lines 35-48).

26. Regarding Claims 18-20, Childs teaches that the metastable dispersion is fabricated by dispersing a polymer in a liquid phase comprising one or a plurality of

liquids ("A spinning solution is prepared by by dissolving ... cellulose acetate propionate in ... acetone" Column 9 Lines 70-75).

27. Regarding Claims 11-14 and 27-29, Childs teaches

- that the collector is grounded (as indicated by the "grounded" symbol drawn to Figure 1 Item 19),
- that the orifice is a capillary tip and has a diameter between about 10 nanometers and 100 micrometers (Table No. 4 in Column 9, where Samples fall between 40-75 micrometers, dimensions such that the Examiner considers the orifices to inherently comprise a capillary tip), and

that the dispenser is fabricated of glass ("spinneret constructed in part of a dielectric material such as glass" Column 5 Lines 28-35).

28. Regarding Claim 30, Childs teaches that the electric voltage applied to the electrode is between about 5 kV and 25 kV (Column 9 Lines 52-53). While Childs does not explicitly teach that the electric voltage applied to the electrode is between about 20 kV and 40 kV, it would have been obvious to one having ordinary skill in the art at the time of the invention to operate within the claimed range, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Bosch*). One would have been motivated to operate at high voltages in at least the upper end of the range of Childs (i.e. 20-25 kV) for the benefit of ensuring a field having flux density sufficient to disrupt the spinning solution so that the fibers may be formed (as per Column 9 Lines 53-61).

29. Claims 3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US 2003/0054035) and Kleinmeyer et al. (US 2002/0089094), and as being unpatentable over Childs (US 2,338,570) and Kleinmeyer et al. (US 2002/0089094), as both are applied to Claims 2 and 16 above, respectively, and both separately in view of Lee et al. (US 2002/0122840).

30. Regarding Claims 3 and 17, the previous combinations both teach a source of electric potential as applied above.

However, neither of the previous combinations explicitly teaches that the source of electric potential is a direct current battery.

In analogous art pertaining to electrospinning, Lee et al. teach that a source of electric potential is a direct current battery ("The high voltage generator 40 outputs DC voltage … and has an anode output terminal … and a cathode output terminal" [0052]) for the benefit of providing polarities such that the discharged polymer fibers are piled stably (as per [0054]).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine either previous combination with Lee et al. for the benefit of providing polarities such that the discharged polymer fibers are piled stably.

31. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US 2003/0054035) and Kleinmeyer et al. (US 2002/0089094) as applied to Claim 1 above, and in view of Childs (US 2,338,570).

32. Regarding Claim 12, Chu et al. teach that the spinnerets/dispensers should be electrically isolated [0211].

However, the previous combination is silent on materials of construction for the dispensers.

In analogous art pertaining to electrospinning, Childs teaches that dispensers are made of glass for the benefit of providing an electrically insulating material that prevents buildup of metastable dispersion on the orifice (Column 6 Lines 53-75).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the previous combination with Childs for the benefit of providing an electrically insulating material that prevents buildup of metastable dispersion on the orifice.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

34. Soane (US 4,917,455) cites that preferential orientation of fibers may be achieved by an imposed electric field during electrospinning.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN OCHYLSKI whose telephone number is 571-270-7009. The examiner can normally be reached on Monday through Thursday and every other Friday from 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rmo

/Philip C Tucker/
Supervisory Patent Examiner, Art Unit 1791